WORKSHOP ON EU NICKEL RESTRICTION

Articles in direct and prolonged contact with skin

Brussels, June 2015

Meeting report

Nickel INSTITUTE

knowledge for a brighter future

Executive summary

As the Workshop on the **EU Nickel Restriction**, organised in Brussels in June 2015 by the Nickel Institute, came to a close, there was a general consensus that it had provided an effective forum for participants to discuss a range of nickel-allergy related topics. Over the course of the day, many perspectives related to Nickel Allergic Contact Dermatitis (NACD) and the EU Nickel Restriction were debated, with calls for such a gathering to become a regular event.

The workshop brought together over 50 participants from a wide range of stakeholders, including representatives from EU institutions, national authorities, dermatologists, industry, standards authorities and testing experts. The objective was to provide stakeholders with an open platform to share views, experiences and concerns as well as discuss the achievements and challenges ahead, 20 years after the adoption of the EU Nickel Directive.

In the opening presentation of the workshop, Enrique Garcia-John, an official of the European Commission stated that while nickel is a major cause of contact dermatitis amongst the EU population, he welcomed the fact that the incidence of NACD had decreased since the introduction of the Nickel Directive some 20 years ago.

With a focus on NACD and the EU Nickel Restriction, the workshop allowed discussion about the interpretation of the term "**prolonged skin contact"**. During his presentation Garcia-John outlined the work by ECHA that led to a definition of the term. He spoke about ECHA's ongoing project to develop additional guidelines which will include a non-exhaustive list of articles to be considered within the scope of the restriction, due for completion in 2016.

NiPERA's Kate Heim informed the meeting about a new research project aimed at further clarifying the definition. The new study seeks to **determine the amount of time needed to elicit a dermal reaction** in individuals by patch testing nickel-sensitised volunteers. The results are expected to be available by the end of 2015.

On the clinical side of the debate, Gentofte University Hospital's Jacob Thyssen referred to NACD as a "global health issue" and called for **greater enforcement of the regulations** at a European level together with the use of appropriate alloys. He also stated that an area of focus should be **body piercings and non-compliant jewellery as they carried the main threats** as the primary cause of nickel sensitisation and NACD.

Hermann-Josef Thierse, from the German Federal Institute of Risk Assessment, noted that there are **still a number of open questions** that need to be addressed in relation to NACD. In particular there was the question of why some people and not others become allergic to nickel. However, he recommended to follow current European nickel restrictions and to consider BfR statements (Bundesinstitut fuer Risikobewertung / German Federal Institute for Risk Assessment) concerning human nickel contact with consumer products.

In the search for more information, Kate Heim called for **more case reports** to be published to support those already in the public domain. In addition, she thought it would be helpful to have an estimate of the **prevalence of nickel-hyper-sensitive people** in the population.

Along the same lines, following a detailed presentation about the work of the Birmingham Assay Office (BAO) by Dippal

Goals of the day

- Provide the most recent update on the latest EU activities relevant to the implementation of the Nickel Restriction
- Share up-to-date knowledge on NACD
- Create a forum for cooperative and constructive communication between stakeholders regarding their practical experiences, challenges, concerns, expectations, current EU developments and potential implications
- Introduce the Nickel Institute's new scientific research project.

Manchanda, there was a call – initially by Torkil Menné – for such positive stories and relevant data about **what industry is doing to tackle NACD**, to be made available to a wider public.

In his overview of the properties of nickel-containing materials and their uses in many applications essential for a modern economy and daily life, Nickel Institute's consultant, Peter Cutler, stressed that it is **nickel release from an item in direct and prolonged contact with the skin, and not nickel content, which influences the potential to cause NACD.**

Manchanda agreed that nickel release is the key issue and stressed that multiple factors (e.g. surface finish, cracks and porosity in plating, metallurgical treatments) affecting nickel release must be taken into account. He reported on the challenges and the work done by CEN TC 374 WG1 to improve the EN 1811 standard, stating that the current approach to compliance is based on random sampling and testing of finished products according to EN 1811:2011.

Bringing the perspective of hand tool manufacturers, Hazet-Werk's Sandra Müller explained why nickel is used in hand tools manufacturing and where nickel/chrome plating play an important role. Müller argued strongly that **hand tools do not need to be and should not be considered within scope of the EU Nickel Restriction.** She pointed out that their inclusion would impose technical and financial burdens for a whole industry, to solve a problem which does not seem to be a real issue in practice.

Ansgar Wennemer reported on the testing activities carried out by TÜV Rheinland in relation to implementation of the Nickel Restriction. He highlighted the **complexity and the variety of the practical challenges of testing the products' nickel release.**

CEN TC 347's Martin Baker gave a succinct overview of the history of European Standards developed to support the Nickel Directive. In the panel discussion, he called for **all stakeholders to be represented on Standards committees and he particularly requested a dermatologist's voice** at such meetings.

Baker also recommended that workshops of a similar nature should be held regularly to bring all interested parties together to exchange ideas and views. Closing the event which had been moderated by toxicology consultant David Basketter, Nickel Institute President, David Butler confirmed that the Nickel Institute would be interested in continuing with such workshops in the future.

Key points

- A robust definition of direct and prolonged contact, in relation to NACD is important and new scientific research is ongoing to determine the amount of time needed to cause a dermal reaction in nickel-sensitised individuals.
- There are still gaps in our knowledge about why some people become allergic to nickel and others do not.
- The major cause of NACD is body piercings and this is where the focus should be on enforcement of the existing restriction so as to reduce incidence.
- The prevalence of nickel allergy in the general population is due to the frequency and types of exposures to nickel-releasing materials (e.g. fashion jewellery) rather than to the strength of nickel as an allergen.
- Testing articles is complex with multiple factors that need to be taken into consideration.
- Standards committees need to have effective representatives from all sectors, including dermatologists.
- Nickel release from an article is what influences the potential to cause NACD and not nickel content.
- Restrictions should take into account real risks – focus on real issues rather than solving issues which do not exist in practice.
- An exchange of information between stakeholders is helpful to explain what each is doing to tackle NACD and increase understanding.
- Turning this initial workshop into a regular event would be useful to provide a neutral forum for stakeholders.

David Butler, President, Nickel Institute

1. Setting the scene

Opening the workshop, the Nickel Institute's President **David Butler** reminded the audience, comprised of representatives of the European Commission, industry, dermatologists, researchers, experts from standardisation bodies and testing firms, that the Nickel Directive had been introduced just over 20 years ago. The workshop was therefore a timely opportunity to look back over the past two decades of experience. Butler expected the day to reveal the achievements, perspectives and – importantly – the challenges ahead.

Focusing on the media coverage of nickel, Butler said that about 20% of it was related to nickel allergies and was generally of a negative nature. With Nickel Allergic Contact Dermatitis (NACD) being a reputational issue for the nickel industry, Butler stated that it was necessary to examine the implementation of the EU Nickel Restriction.

Butler stressed the importance of NiPERA, the Nickel Institute's scientific research arm and their involvement in the NACD issue. He emphasised that NiPERA is an independent entity and that the Nickel Institute is committed to supporting science-based regulation backed by peer-reviewed literature. Butler also referred to the Institute's Position and its key messages concerning the appropriate use of nickel in appropriate applications.

Moderated by toxicology consultant **David Basketter**, the speakers at the Nickel Institute's workshop were **Enrique Garcia-John** (European Commission), **Peter Cutler** (consultant to the Nickel Institute), **Kate Heim** (NiPERA), **Jacob Thyssen** (Gentofte University Hospital), **Dippal Manchanda** (Birmingham Assay Office, on behalf of the World Jewellery Confederation, CIBJO), **Sandra Müller** (Hazet-Werk, on behalf of the German and European hand tools industry), **Hermann-Josef Thierse** (German Federal Institute for Risk Assessment), **Martin Baker** (Chair of CEN Technical Committee 347 "Methods of analysis of allergens" WG1 "Metals"), and **Ansgar Wennemer** (TÜV Rheinland).

Basketter opened the proceedings by stating that the day's focus would be on NACD and the EU restriction on nickel in consumer articles intended to come into direct and prolonged skin contact.

The Nickel Institute's Position on Nickel Allergic Contact Dermatitis (NACD)

1. Appropriate materials should be used in appropriate applications to avoid adverse health effects, including NACD.

2. Three simultaneous conditions must occur to trigger NACD in sensitized individuals or make non-nickel allergic individuals nickel allergic: 1. direct skin contact with a nickel-releasing item + 2. prolonged skin contact with a nickel-releasing item + 3. a sufficient amount of nickel must be released and absorbed into the skin to cause a reaction.

3. It is the amount of nickel released from the article, not the nickel contained in the article, which determines the potential for NACD to occur.

4. Many nickel-containing materials, such as high quality stainless steels containing 9-28% nickel, do not release nickel at a level to cause NACD.

5. For sensitised individuals, NACD may cause discomfort such as itching and rash, which will resolve itself when contact ceases. NACD is not life-threatening and cannot cause anaphylactic shock.

http://www.nickelinstitute.org/en/NiPERA/HumanHealthScience/FS1-AllergicContactDermatitis.aspx

2. History of nickel regulation and related standards

Dr. David Basketter, moderator of the workshop

During the day, an official of the European Commission, **Enrique Garcia-John**, CEN's **Martin Baker** and the Birmingham Assay Office's **Dippal Manchanda** painted a comprehensive picture of the developments over the last 20 years. They traced the history from 1994 when the use of nickel in consumer articles was first regulated at the EU level (Directive 94/27/EC), through to the current work being conducted by the European Chemicals Agency (ECHA) in relation to a new definition of 'direct and prolonged contact with the skin', the supporting guidelines and articles types covered.

2.1 A HISTORY OF NICKEL REGULATION

Kicking off the workshop, Garcia-John stated that nickel is a major cause of contact dermatitis amongst the EU's population. Overall, he reasoned that 10-20% of women were sensitised compared to just 1-3% of men, but with large variations by country. It appeared, for example, to be more prevalent in southern European countries.

On the positive side, Garcia-John welcomed the fact that in some countries (e.g. Denmark, Sweden and Germany) the prevalence of nickel-sensitisation has decreased since the introduction of the Nickel Directive in 1994. It had been inspired by earlier Danish measures in 1990 and had established limitations on the use of nickel in body piercings and other products that would come into direct and prolonged contact with the skin.

The allowable nickel content (for piercing materials) and rates of nickel release (in other articles) were based on the studies available at the time, including studies conducted in 1987-88 by Torkil Menné and colleagues on nickel release and reactivity of nickel alloys in nickel-sensitive individuals. Garcia-John recalled that the prime objective of the legislation was to prevent individuals from becoming sensitised to nickel as well as to protect a substantial part of the nickel-sensitised (allergic) population from having a nickel-allergic reaction. The aim was to protect the majority, but not all, of those sensitised to nickel.

Expanding on the introduction of the Directive, Baker noted that there had been a seven-year gap prior to its full implementation in 2001. This had been due to the time needed for the development of the relevant standards, their publication in the EU official journal and the Directive's entry into force, following a two-year adjustment period.

Reasons why the prevalence of NACD may differ by country within the EU

1. The length of time for which the Directive has been applicable within a country
2. The quality of materials used and the production processes of some manufacturers
3. The enforcement of the Directive

ECHA definition of 'prolonged contact with the skin' as endorsed by the competent authorities (CARACAL)

Prolonged contact of nickel with the skin is when it is potentially more than

- 10 minutes on three or more occasions within two weeks, or
- 30 minutes on one or more occasions within two weeks.

http://echa.europa.eu/documents/10162/13641/nickel_restriction_prolonged_contact_skin_en.pdf

Enrique Garcia-John, European Commission

Martin Baker, CEN

In 2004, the European Commission reviewed the Nickel Directive because of concerns that piercing materials made of high grade stainless steel used in surgical implants (ISO 5823) that did not cause NACD would not comply with the original nickel content limit of 0.05%. This content restriction was therefore removed and replaced by a nickel release rate of 0,2 µg/cm²/week for post-assemblies in piercings. At the same time, CEN (European Commitee for Standardization) was requested to review the EN 1811 standard, which is the reference test method for release of nickel, and reduce the 'adjustment factor' of 0.1 which had been introduced to deal with testing uncertainties. In 2009, the restriction previously defined in the Nickel Directive was incorporated in Annex XVII to the REACH Regulation (Annex XVII, Entry 27) .

The restriction had a narrative description of its scope, based on 'direct and prolonged contact with the skin' together with a non-exhaustive list of articles as stated in Appendix D. Garcia-John explained that over the years, there had been discussions as to how to interpret the term "prolonged skin contact". It has been clarified, for example, that mobile telephones although not listed in the legislation were covered by the restriction and should comply with the conditions set in Entry 27 of Annex XVII to REACH.

Indeed, the meaning of 'prolonged' had first been discussed in 2010 at CARACAL (Competent Authorities for REACH and CLP) and a definition produced via a subsequent paper. The initial definition had stated : "The term prolonged should be understood as covering a daily overall contact with the skin of more than 30 minutes continuously or one hour discontinuously" (CA/85/2010). Following a request from the member states for further scientific backing, the Commission requested ECHA to produce a definition of 'prolonged skin contact'. This was presented by ECHA [see box page 5] and endorsed by CARACAL in April 2014.

Later in 2014, the Commission requested ECHA to provide additional guidance and develop a list of specific articles to be considered in the scope of the restriction, in addition to those already listed in the legislation. This work started in 2015 and comments have been received from various stakeholders. A draft guideline is being prepared and there will be further consultation prior to potential endorsement by CARACAL expected in early 2016.

2.2 A BRIEF HISTORY OF STANDARDS

In 1993, the European Commission mandated CEN to develop test methods in order to determine compliance of articles with the Nickel Directive. Baker presented a brief history of the European standards developed in support of the Nickel Directive. In the early 1990s, a number of CEN technical committees and working groups had been created, with Sweden playing a prominent role. Over the next 20 years or so, Denmark, Germany and Switzerland played lead roles in the development of these standards.

Over the course of the day, the various test methods were discussed. EN 1811 was introduced to determine the release rate of nickel from articles intended to come into direct and prolonged contact with the skin initially, and later from post-assemblies intended to be inserted into body piercings.

EN 12472 was developed and is required to simulate two years wear of coated items. The CR 12471 test is also known as the DMG (dimethylglyoxime) test and its validity was the subject of some debate during the workshop. Baker reasoned that CR 12471 would save time and money since if an article failed this test, it would certainly not pass EN 1811. Several attendees cast doubts on the validity of the DMG test as it was known to produce 'false positives'. Thyssen commented that the DMG test was a first indication only and agreed that it was not always conclusive. CR 12471 was described by some participants as a qualitative test "quick, simple and cheap", but not suitable for determination of compliance with the Nickel Directive.

Dippal Manchanda, Birmingham Assay Office

2.3 A MARKET PERSPECTIVE ON STANDARDS AND THE RELATED TESTING

Manchanda looked at EN 1811:2011 and examined the consequences and impact of CEN's revisions of the standard (EN 1811:1998) made in order to address the issues of poor repeatability and variations within the same batches of test articles. CEN had introduced the concept of 'measurement uncertainty' instead of the aforementioned 'adjustment factor' and the various changes had been expected to bring tighter limits and improve precision and better repeatability to the EN1811. He noted that one objective had been to increase the trade's confidence in the standard.

The revised standard EN 1811:2011 came into force in April 2013 and Manchanda stated that it regrettably had changed nothing; poor repeatability and variations within the same batches remained. In addition, there were high failure rates of alloys which were considered to be safe and were previously compliant under EN1811:1998. Manchanda reasoned that with many alloys now failing EN 1811:2011, a high number of special category alloys were being produced to meet the new standard, while the majority of retailers Manchanda was aware of were choosing nickel-free alloys. Overall, he concluded that there had been an increase in the cost of making items included under the Nickel Restriction, decreased confidence in the 'standard' and confusion among the enforcement authorities due to the introduction of a 'No Decision Category'.

Despite this, Manchanda argued that the CEN Committee could not have done any better in their task as the amount of nickel released after EN 12472 followed by EN 1811 tests may be influenced by a number of factors (see box below). Manchanda further reasoned that these production-related issues were beyond the control of the CEN Technical Committee.

As the current approach is based on random sampling, Manchanda stated that it did not demonstrate that all the pieces produced in the same batch possessed the same resistance to corrosion. Manchanda therefore called for a strict monitoring process, noting that both high street retailers and enforcement authorities have a role to play. He also recommended the introduction of a specific voluntary hallmark for nickel release tested items by accredited test houses. This could increase consumer confidence and offer the honest manufacturer a competitive advantage.

Factors that can influence the amount of nickel released during testing:

1. Surface finish
2. Cracks and porosity in plating
3. Metallurgical treatments such as annealing, etc.
4. Presence/absence of certain elements (e.g. sulphur and manganese)
5. Contamination with nickel during the fabrication process
6. Inadequate surface area of sample tested

2.4 Questions for Enrique Garcia-John and Dippal Manchanda

Referring to the consultation process mentioned by Garcia-John for the list of types of articles to be included in the Nickel Restriction, the Nickel Institute's **Marco Vallini** inquired as to who would manage the next steps – would this be the Commission or ECHA? Garcia-John stated that it was highly likely that ECHA would manage the consultation process on the guideline as this would seem to be the most practical way forward. Endorsement would of course be via the member states competent authorities (CARACAL) after consultation with other stakeholders, including industry.

Baker asked Manchanda for more detail as to which materials – alloys or plated materials – were generally failing the EN 1811 test. Manchanda stated that samples of low-nickel alloys (0.5%-5% nickel) would always fail; however, he added, if a sample had 99% nickel or if it had a smooth finish (to 6 microns) it would not fail the test. Manchanda added that plating failures were usually due to contamination in the manufacturing process and argued that the facilities in countries such as China might not always be of the required level of quality.

Menné was impressed by Manchanda's presentation and asked for such positive stories and relevant data, in terms of the detailed tests being conducted, to be published in respected dermatology journals. He noted that dermatologists often tended to tell a negative story and that publication of this information and data could be an important way to change attitudes.

3. Where and why nickel is used?

Dr. Peter Cutler, Nickel Institute

Peter Cutler, consultant to the Nickel Institute reminded participants of the properties and wide range of uses of nickel. With over two thirds of all nickel production being used to make stainless steel, he underlined how nickel is essential in so many applications in daily use and has an essential role in innovations. He explained the link between corrosion and NACD which would be described in more detail by Kate Heim later in the workshop.

Nickel provides strength and flexibility

Nickel provides corrosion resistance

Nickel provides high temperature resistance

Nickel is fully recyclable

Nickel is used to store energy

Nickel – an overview

- A naturally-occurring element, essential to plants; present in air, soil, water & food.
- High melting point, resists corrosion, ductile.
- Readily available, fully recyclable.
- Stainless steels and nickel alloys are widely used in many industries.
- 67% of nickel is used in stainless steel.
- Enhances corrosion resistance and mechanical properties of many alloys.
- A critical part of items such as automotive turbochargers and gas turbines as it cannot be substituted.
- Nickel is essential today and tomorrow.

4. The NACD mechanism

4.1 The Sensitisation process

NiPERA's **Kate Heim** reviewed the nickel sensitisation process. As a naturally-occurring substance, Heim stated that nickel was essential to all plants and some animals. Approximately 12-15% of women and 1-2% of men are sensitised to nickel. She emphasised that although NACD may lead to pain and discomfort, it is not life threatening and does not cause anaphylactic shock like some common allergens (e.g. peanuts). Heim said that NACD could be managed by avoiding direct and prolonged contact with items that could potentially release a sufficient amount of nickel ions to cause an allergic reaction. Furthermore, these ions had to cross the skin barrier, i.e. go through the dermis, for the immune system to react.

Heim described nickel sensitisation as a Type IV allergic reaction[1] where the induction phase primes and sensitises the immune system if sufficient nickel ions (allergen) are present. This creates a "memory" of nickel for future exposure. Once allergic, a person would continue to be allergic. This would be followed by an elicitation phase when the immune system recognised nickel and caused a NACD reaction if there was enough exposure to nickel ions (above the threshold required to cause a NACD reaction). This phase was said to be reversible, i.e. the allergic reaction heals after the exposure stops.

Heim stated that corrosion is necessary for the release of nickel ions to cause an allergic reaction. She added that prolonged contact is required for the necessary corrosion to occur, which requires a medium, e.g. sweat or water. This process of corrosion and penetration of the skin takes time. If the nickel ions are washed off before they are absorbed then there would be no reaction since insufficient nickel would be absorbed to interact with the immune system (e.g. below the threshold).

Heim noted that fewer nickel ions are needed for the elicitation phase (lower threshold) to be evoked than to become allergic) and that the regulations aim to prevent all people from becoming allergic in the induction phase and most people from having an allergic reaction in the elicitation phase, i.e. for those already nickel-allergic.

It was also stated that nickel is a "weak sensitiser" (low potency) as the threshold exposure to cause a NACD reaction (induction or elicitation) is relatively high compared to other allergens. Heim explained that the prevalence of nickel allergy in the general population is due to the frequency and types of exposures to nickel-releasing materials (e.g. fashion jewellery) rather than to the strength (potency) of nickel as an allergen.

Regarding the issue of materials in contact with skin, Heim stressed that nickel release (not content of the material) is the relevant factor for assessing the potential to cause NACD. For instance, some nickel-containing materials (e.g. most stainless steels, some coated materials) are appropriate for use where there is prolonged skin contact since they comply with the EU Nickel Restriction by releasing very low amounts (if any) of nickel ions.

For NACD to occur, three conditions must be met

1. Direct contact with skin
2. Prolonged contact with skin
3. Sufficient amount of nickel ions released and absorbed through the skin

1. Nickel is type IV allergen, meaning it results in a delayed-type reaction mediated by antigen-specific-cells in the immune system.

Dr. Kate Heim, NiPERA

4.2 NiPERA's Scientific research project

Although most of the science relating to NACD is well-established, Heim argued that there had still not been sufficient relevant research in regard to the definition of 'prolonged contact', i.e. the time needed for continuous contact with a high nickel-releasing item to develop an allergic reaction.

As a result, NiPERA has initiated a scientific research project to determine the amount of time needed to elicit a dermal reaction in nickel-sensitised individuals. The results are expected to be available in November 2015 and will be shared with the regulatory authorities for consideration in the context of ongoing activities around the current definition of "prolonged skin contact". The results will also be published in a peer-reviewed journal.

4.3 Questions for Kate Heim

During her presentation, Heim said that in NiPERA's scientific research project patch-testing of nickel-sensitised individuals would be performed with nickel metal discs. Manchanda suggested that discs with a low percentage of nickel might be more effective in the testing as the nickel release would be higher. He added that the majority of fashion jewellery used low-level alloys and they were more harmful.

Heim expressed concern over the blanket statement that low nickel alloys would fail EN1811:2011 as that depended on the alloy. She added that the pure nickel discs had been chosen for the tests as a reasonable worst case for nickel release. Heim, however, welcomed the comments and noted that the research project's patch testing had not yet started and the patch test materials could be reviewed as a result of the workshop discussions.

In regard to the proposed study, Spectaris e.V.'s **Carsten Leutloff** asked if there were concrete definitions for 'the sufficient amount of nickel' and 'prolonged contact'. Heim stated that there was not enough data available to accurately assess what 'prolonged contact' meant. While ECHA had commissioned a review, there was still not sufficient relevant information which is why NiPERA is conducting a human patch test study. As for the amounts of nickel being released, Heim said they knew what the threshold was for nickel salts but that it was not clear how that threshold would be achieved based on the contact of metallic articles with the skin.

5. A clinical dermatology perspective on NACD

The Gentofte University Hospital's **Jacob Thyssen** provided a clinical dermatology perspective on NACD, which he described as a "global health issue". He introduced his outlook by stating that severe cases of consumer and occupational allergic nickel dermatitis were still being observed. Thyssen gave examples that included spectacles where the protective layer had vanished in places after 30 months, belts that released nickel and the sensitisation of people working with computers and mobile phones. Thyssen called for major players producing such items to take responsibility for their actions.

Looking at figures for the general population, he showed a steady increase of nickel allergy since the 1960s and emphasised that piercings were crucial, with heavy incidences of NACD among people wearing necklaces and earrings.

Work at the University of Copenhagen in the 1970s had shown high rates of permanent disability from hand dermatitis caused by both consumer jewellery and from occupational hazards in women sensitive to nickel, chromium and cobalt. However, Thyssen showed data from Denmark and Germany that indicated a significant decrease of nickel allergy and dermatitis following the introduction of the EU nickel regulation.

This was particularly the case for younger women but Thyssen argued that the prevalence of nickel allergy was persisting and has now stabilised. He noted that, after the introduction of the regulation there were fewer strong reactions but still some medium reactions.

Thyssen ended with a concern and a warning. With an increase in implants, he said that people wanted these to be nickel-free if they were possibly allergic to nickel. In addition, people wanted to be patch-tested before implant surgery. Thyssen argued that patch testing and nickel-free implants would be expensive, and would be increasingly so given the demographic breakdown, when nickel-free implants were not necessary and most people would not react to current nickel-containing implants. It would also be difficult to interpret from the results of the patch testing if a person would react to implants containing nickel. His conclusion was that it was time for safer alloys to be made available. Nickel, he added, was very important but regulations had to be enforced at the European level.

Dr. Jacob P. Thyssen, Gentofte University Hospital

Reasons why NACD is persisting

- The initial regulation was too weak (adjustment factor)
- Violations of the regulation
- A lack of control by the relevant authorities
- The arrival of new articles that caused nickel allergy
- Sensitisation in older people before the regulation kicked in
- (Occasionally) occupational practices.

Dr. Ansgar Wennemer, TÜV Rheinland

6. The issues of practical testing, enforcement and articles subject to the EU Restriction

6.1 Testing Perspective

TÜV Rheinland's **Ansgar Wennemer** looked at the practical aspects of testing the rate of nickel release. He explained that his organisation tested products ordered by retailers, including 'bling' jewellery, watches, metal parts of clothing and bags, spectacles and toys. In general, Wennemer stated that his team tested articles that were continuously in contact with the skin for several hours, but he added that sometimes – with toys for example – they were requested by producers and retailers to test for nickel release even though it was not apparent that children would touch the same part of a toy continuously.

Turning to the technologies used to produce the required surfaces of the tested articles, Wennemer differentiated between a) nickel-containing electroplating and b) nickel-free electroplating (even though this was described as nickel-free, Wennemer stated that products could contain up to 10% of nickel which for him 'made no sense'). In the former, copper and nickel layers were used to get a semi-gloss finish followed by chromium or gold to reduce the nickel release. However, Wennemer said that the use of chromium could cause problems and lead to cracks and variations and the necessity to add a porous middle layer.

In the so-called nickel-free articles, the same base materials were used (e.g. iron, copper alloy, die casting etc.) with a layer of bronze followed by a top coat of gold, platinum or palladium etc. This meant that more preparation/polishing was required but the nickel release results were better for the so-called 'nickel-free' products. This was because the nickel-containing electroplating often led to a lack of homogeneity on the surface.

Agreeing with Manchanda in regard to stainless steel used in piercings, Wennemer said it was important to use high-alloy stainless steels (18/10, 18/8) as the use of low-alloy options (2-7% nickel) would require more polishing with a subsequent higher release of nickel.

Looking back over the testing results in the past five years, he said that in 2011, the failure rate had increased dramatically due to the removal of the 'adjustment factor'. Since that time, he said, the production methods had improved and failures in internal tests conducted by TÜV had dropped to around 16%.

6.2 Market Perspective

Hazet-Werk's **Sandra Müller** gave an engaging account of the European hand tool industry's views on the current testing procedures. She explained where and why nickel is used and emphasised the importance of the nickel/chrome plating in hand tool manufacturing. She highlighted the huge variety of hand tools on the market, explaining that there are approximately 6,000 different types. Müller argued strongly that hand tools did not need to be regulated as contacts with the skin were generally very short and such contact was usually with the less sensitive inner palm.

In addition, she highlighted that the EU Risk Assessment report (2008) on nickel did not find any concerns about hand tools either for workers or consumers. Where tools failed the EN 1811 test, Müller argued that this was due to high migration rates at critical spots that were outside the contact zone with the skin.

Sandra Müller, Hazet-Werk GmbH&Co. KG

Müller concluded that, as there had not been any reports of nickel-related problems with hand tools, they should not be considered to fall within the scope of the restriction[2].

Moreover, she argued that if they were to be covered, test requirements had to be suitable. In response, Menné said that NACD had been seen on people using hand tools. He reasoned that this could be due to low quality tools at small local companies and he thought that such tools could not be excluded from testing. However, Menné did agree there was a need for high quality products across the board.

Manchada, on behalf of the CIBJO (World Jewellery Confederation), noted the common complaints of the revised EN1811 testing as being poor repeatability and considerable variation in the test results between samples from the same batch. This poses problems for both customers and laboratories. In addition, high failure rates of alloys which previously used to be compliant under EN1811:1998 were problematic since review of material choices were needed. The inclusion of a "No decision category" in the revised EN1811 protocol was impractical and nonsensical. All of these things caused confusion within the trade and reduced their confidence in the standard. CIBJO worked hard to get these concerns noted and the issues are in the process of being addressed by CEN.

2. No tool-related case reports from professional users to the *Berufsgenossenschaft* (the German Employer's Liability Insurance Association for the metalworking and woodworking industry) and no tool-related case reports from the German consumer's community www.nickelfrei.de

Dr. Hermann-Josef Thierse, BfR

6.3 Implementation and Enforcement

The German Federal Institute for Risk Assessment's (BfR) **Hermann-Josef Thierse** opened his remarks by saying that after working in this area for 16 years, he still did not have a good explanation as to why some people become allergic to nickel.

Highlighting that it was important to see the whole picture, Thierse stated that nickel is abundant in nature, making up around 7% of the earth's core. It was therefore impossible to avoid exposure to nickel and he emphasised that some plants, foods and bacteria all have high tolerance to the metal. Furthermore, Thierse showed that nickel was present in the human body – blood, urine, gut etc.- even before any prolonged contact between nickel and the skin.

Thierse gave some examples of opinions adopted by BfR – "nickel in tattoo substances may induce allergies" and "piercing may lead to nickel sensitisation". Ending his talk with a list of outstanding questions, Thierse focused on matters such as:

- What are the naturally occurring concentrations of nickel in the human body?
- Which people develop an Allergic Contact Dermatitis (ACD); who is susceptible?
- How does the current definition of "prolonged skin contact" fit into the contemporary thinking [about NACD]?

7. The panel debate

7.1 A BENEFICIAL DAY AND A CALL FOR FURTHER DEBATE

Opening up the debate from the floor, Heim said it had been beneficial to see the whole picture with the correlation of the clinical, hazard and exposure aspects of NACD. Thyssen had welcomed the wealth of information that had been presented during the day and reasoned that there could be a great benefit in speakers being willing to share and examine the information in more detail.

Basketter was of the opinion that clinicians were frequently not believed by scientists and technicians and he asked if it was the case in this field. Heim said she didn't doubt the presence of clinical reactions but she wanted to see more case reports to be published to go alongside what was already in the public domain. In addition, she noted that it would be helpful to know what is the prevalence of nickel hypersensitive people in the population. Basketter argued that it was difficult to get articles about NACD published as it was a topic that was, ironically, a well-known problem. Menné stated that real evidence about nickel alloys had been published, including clinical studies, and that it was "well founded", for example, when the Danish project started, they calculate potential benefits of savings in the country's healthcare system due to the prevention of ACD at +/- 1 billion euros. As Danes account for about 1% of the EU population, Menné felt that it was a useful job. Heim agreed and clarified that she wanted case reports of the specific articles causing NACD to be published. This would allow the information- causes and frequency – about the main sources of NACD to be made available to a wider public. Thyssen agreed and stated that often these examples, e.g. regarding computer tablets, showed that some major manufacturers were either not following the correct quality procedures or just wanted to make a fast buck.

Baker insisted that the progress made in the workshop needed to be continued as such exchanges of information were essential. He therefore invited the Nickel Institute to carry on examining all aspects of NACD so that all parts of the puzzle could be understood. Baker suggested that perhaps there could be more NACD workshops in the future.

7.2 Calls for more information and research

Roger Hooper, a consultant to the Nickel Institute, referred to items such as earrings and necklaces which were covered by the standard and asked about other items with much shorter contact times that were now being considered for inclusion in the EU Nickel Restriction. As 'prolonged contact' was a key part of the EN 1811 standard definition, and a key topic of the day, he asked Menné for his views on the subject.

Menné said he could not give a clear-cut answer. Even if technical data was available, he thought that more clinical information was needed. Baker reminded the panel that the required exposure for an NACD reaction was reduced if an individual was already nickel sensitised but he emphasised that there was still no answer as to how much nickel had to be released and for how long, before an individual became sensitised.

Baker asked for more facts as to which type of products and materials were failing the EN 1811 test. He pointed out that the data in the RAPEX notifications concerning nickel did not have sufficient detail about which parts of the articles and what type of materials were failing. Baker suggested that the EU could ask member states for feedback as it was difficult for CEN to receive that data directly.

For Thyssen, it appeared that piercings and low quality products carry the main threats as sources of NACD and that the focus should be on those two areas. He stated that he was not afraid when he touched a door handle or when he handled his keys. Thyssen wanted to pin down the real causes of NACD.

Basketter reasoned that it was possible that the jewellery industry had a myriad of SMEs that may be unaware of the regulations. Wennemer argued that the 'bling' jewellery was dominated by a few major suppliers but he was not aware of the percentage of imports – that may indeed be "manufactured in a garage". This prompted Heim to turn to enforcement in general and China in particular. She stated that enforcement was a key issue and that articles coming in from China should be further scrutinized.

Baker referred to the need of having dermatologists contributing to the work of the CEN working group. He said that in the past dermatologists were involved but are no longer participating in the activities of the working group. Baker added that there were practical problems – such as time and money – but he argued there would be major benefits in having all stakeholders present at such meetings.

8. Recommendations from the Workshop

During the day a number of recommendations had been made by the speakers and more came as a result of the panel discussion. The following is a non-exhaustive list:

1. Speakers should share information contained in the presentations, and the related data, so it can be examined and discussed in more detail. (All)

2. More workshops of a similar nature should be held as they represent a way of bringing the relevant people together to exchange ideas and views. (Baker)

3. There should be a focus on piercings and low quality products as they appeared to be the main causes of NACD. (Thyssen)

4. There would be a benefit in making a request to the EU to contact member states so that CEN and other stakeholders could receive more information about which parts of articles and what type of materials were failing nickel release tests such as EN1811. (Baker)

5. Dermatologists should be involved in the activities of the CEN Technical Committees; such working groups should contain representatives of all stakeholders. (Baker)

6. The current REACH regulation referred to “two years of normal use” and further studies should be undertaken in this area in order to ascertain if there would be problems after this length of time. (Baker).

7. The positive stories, in terms of the detailed tests being conducted and what industry is doing should be published in respected journals. (Menné, Thyssen)

8. There should be a strict monitoring process and the introduction of a specific voluntary hallmark for nickel release tested items by accredited test houses. This could increase consumer confidence and offer honest manufacturers a competitive advantage. (Manchanda)

9. Further investigation of the correlation of clinical reactions, nickel release, and exposure should be conducted by communication between relevant parties. (Heim)

It’s a wrap...

Stating that he had found the day to be enlightening, Butler brought the day to a close. Having heard the various comments from the panel and the floor, he said that the Nickel Institute was keen to continue with such workshops. Noting that the Institute has been a little absent from the debate in recent years, Butler said this discussion was important for the industry and for the wellbeing of civil society.


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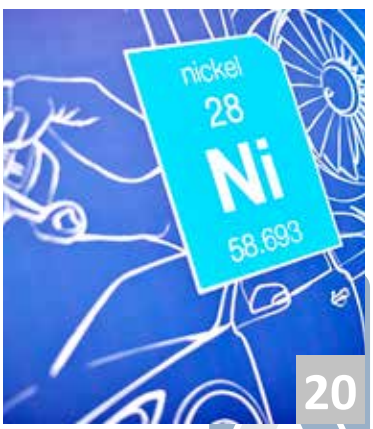
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Program of the day

9.00-9.30 - Coffee and registration

09.30-09.45	1. Welcome and introduction *Nickel Institute and NiPERA*
09.45-10.15	2. From the Nickel Directive to the REACH restriction *Mr. E. Garcia-John, DG GROW, European Commission*
10.15-10.45	3. Properties and uses of Nickel: an overview *Dr. P. Cutler, Consultant to Nickel Institute*

10.45- 11.00 - Coffee break

11.00-11.30	4. Nickel sensitization process, data overview and research *Dr. K. Heim, Regulatory Toxicologist, NiPERA*
11.30-12.00	5. Dermatology clinic perspective *Prof. Dr. J.P. Thyssen, Gentofte University Hospital, Denmark*
12.00-12.45	6. Market perspective *Mr. D. Manchanda, Birmingham Assay Office, UK, The World Jewellery Confederation* *Mrs. S. Müller, HAZET-WERK, German Association Tool Manufacturing Industry*

12.45- 13.45 - Lunch

13.45-14.15	7. Implementation and enforcement *PD Dr. H.-J. Thierse, Federal Institute for Risk Assessment, Germany*
14.15-15.00	8. The perspective of standardisation and testing experts *Mr. M. Baker, Convenor, CEN Technical Committee 347 "Methods for analysis of allergens", WG 1 "Metals"* *Dr. A. Wennemer, TÜV Rheinland, Germany*
15.00-15.45	9. Panel Discussion - Q&As
15.45-16.00	10. Conclusions *Nickel Institute and NiPERA*

16.00: end of the meeting, networking coffee and drinks

List of participants

Assay Office Birmingham - The World Jewellery Confederation	Dippal	Manchanda
BIC	Laurent	Beaucher
BIC	Cécile	Blocquel
BIC	Jean-Baptiste	Coiffard
BV Schmuck + Uhren	Ina	Zeiher-Zimmermann
Certottica	Giuseppe	Cortà
Cetehor	Edwige	Soton
Consultant to NI	Peter	Cutler
Consultant to NI	Roger	Hooper
Convenor, CEN TC 347 WG1	Martin	Baker
DABMEB Consultancy Ltd	David	Basketter
Danish Environmental Protection Agency	Maiken	Rasmussen
Demeyre	Maurits	Demeyere
Eramet	Frederic	Gaidou
Eurofer Stainless	Hans	Regtuit
Eurometaux	Caroline	Braibant
European Commission	Enrique	Garcia-John
FEC (European Federation of Cutlery, cookware and housewares)	Matthias	Peters
Federal Institute for Risk Assessment	Hermann-Josef	Tierse
Fondel Metals	Bernard	Rademakers
Forschungsgemeinschaft Werkzeuge und Werkstoffe e.V. (FGW)	Samuel	Zind
Gentofte University Hospital	Torkil	Menne
Gentofte University Hospital	Malin	Glindrad Ahlström
Gentofte University Hospital	Jacob Pontoppidan	Thyssen
Glencore	John	Smillie
Glencore	Sean	O'Sullivan
Hazet-Werk - German Association Tool Manufacturing Industry	Sandra	Müller
Hoganas	Benoit	Gobeaux
Journalist, Rapporteur for the workshop	John	Chapman
Netherlands Food and Consumer Safety Authority	Rog	Adhemar
Nickel Institute	Marco	Vallini
Nickel Institute	Isaline	de Baré
Nickel Institute	Veronique	Steukers
Nickel Institute	Clare	Richardson
Nickel Institute	David	Butler
Nickel Institute	Nigel	Ward
NiPERA	Kate	Heim
Nokia	Ilona	Santavaara
Philips	Tarja	Sivonen
Premec S.A.	Fausto	Conti
Progold	Damiano	Bruttomesso
Progold	Stefano	Rappo
Sheffield Assay Office	Belen	Morales
Smart Practice	Curtis	Hamman
Spectaris e.V.	Carsten	Leutloff
Staedtler Mars GmbH & Co. KG	Alexander	Vyhnal
Swatch Group Quality Management	Erik Jan	Frenkem
Swatch Group Quality Management	Valérie	Thomet
The Royal Mint	Graham	Hartry
The Royal Mint	Scott	Kuperus
Tony Newson Consultant	Tony	Newson
Toy Industries of Europe	Albert	Vallejo
TÜV Rheinland	Ansgar	Wennemer
Umicore NV	Jordi	Agemans
Wieland-Werke AG	Birgit	Twrdek
WirtschaftsVereinigung Metalle	Martin	Wieske

Link to presentations

All presentations made at the workshop can be downloaded at

http://www.nickelinstitute.org/en/KnowledgeBase/Events/20150625-NACDWS.aspx

This link will also allow you to download speakers' biographies and information packs about NACD.

Entry 27, Annex XVII, REACH Regulation

Nickel CAS No 7440-02-0 EC No 231-111-4 and its compounds

1. Shall not be used:

(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/ cm 2 /week (migration limit);

(b) in articles intended to come into direct and prolonged contact with the skin such as: - earrings,- necklaces, bracelets and chains, anklets, finger rings, wrist-watch cases, watch straps and tighteners, rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,

if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm² /week.

(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm²/week for a period of at least two years of normal use of the article.

2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.

3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20130701:EN:PDF#page=233

Let's connect!

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